

K190978 RefleXion Medical Radiotherapy SystemMar 12, 2020
332 days to decisionK190978 · Product code: **IYE** · Radiology
Source: <https://www.510kdatabase.net/k190978/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Apr 15, 2019
Decision date	Mar 12, 2020
Days to decision	332 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Reflexion Medical, Inc.
Location	Hayward, CA, US
Contact	Kathy O'Shaughnessy
510(k) history	3 submissions · 2 cleared · 2020-2025

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